



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20857

REGISTERED MAIL
RETURN RECEIPT REQUESTED

FEB 28 1979

Abraham A. Chaplan, M.D.
Place

Dear Dr. Chaplan:

Notice of Disqualification to Receive Investigational New Drugs

I have reviewed the record of the regulatory hearing conducted by Dr. Mark Novitch on November 15, 1978, relating to your eligibility to receive investigational-use drugs. At the hearing you were unable to offer satisfactory explanations for the deficiencies observed in your clinical investigations of investigational new drugs as set forth in the September 7, 1978, Notice of Opportunity for Hearing on this matter. Therefore, on the basis of all information, I am affirming and adopting the January 17, 1979, Recommended Decision and Report of the Presiding Officer and have determined that you have repeatedly and deliberately failed to comply with the exempting regulations for new drugs for investigational use in that:

1. Patient records for the study which you conducted are inadequate.
2. Patient records for the study which you conducted are inadequate.
3. Patient records for the study which you conducted are inadequate.
4. Patient records for the study which you conducted are inadequate; further, there are inconsistencies between the patient records that do exist for patients in this study and patient case reports prepared for submission to the sponsor.

CMD/

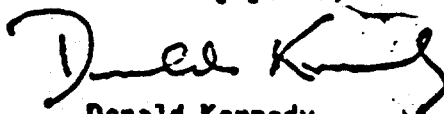
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In accordance with 21 CFR 312.1(c), you are hereby advised that you are no longer entitled to receive investigational new drugs. All such drugs now in your possession should be promptly returned to their supplier.

For your information, enclosed are copies of letters which have been sent to all sponsors of investigations in which you have been named as a participant, notifying them that you are not entitled to receive investigational-use drugs.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Donald Kennedy". The signature is written in a cursive style with a large initial "D" and a long, sweeping underline.

Donald Kennedy
Commissioner of Food and Drugs

Enclosures

cc: HF-1 (2)
HF-2
HFC-4
HFD-1
GCF-1
HFY-1 R/F
HFY-21 (Chaplan Files)
HFA-225
HFJ-1
HFJ-5 (TRAC #7900473)

Department of Health, Education and Welfare
Food and Drug Administration

Report of the Presiding Officer
In the Matter of the Eligibility of
William L. Doss, Jr., M.D. To
Receive Investigational-Use Drugs

INTRODUCTION

This matter is before the Food and Drug Administration (FDA) to determine whether William L. Doss, Jr., M.D., an investigator of new drugs, should be entitled to continue to receive investigational-use drugs. For the reasons given below, it is the recommended decision of the presiding officer that Dr. Doss has failed to exercise his right to a regulatory hearing and that on the basis of the existing record he is no longer entitled to receive investigational-use drugs.

BACKGROUND

Dr. Doss was formerly a clinical investigator of _____ under IND _____. His study was inspected in June 1977, and eight specific deficiencies were found in the conduct of his study. Dr. Doss was offered an opportunity for an informal conference to respond to those deficiencies. The conference was scheduled for December 19, 1977. Dr. Doss did not appear but rather sent two representatives from his clinic to speak for him. Their explanations of the deficiencies were found unacceptable by the Bureau of Drugs, and disqualification as a recipient of investigational-use drugs was recommended.

A Notice of Opportunity for Hearing was sent to Dr. Doss on March 3, 1978. Dr. Doss requested a hearing, and Dr. John Jennings was designated as the presiding officer. Dr. Doss' hearing was scheduled for April 7, 1978, in Rockville, Maryland. On March 23, 1978, Dr. Doss phoned Dr. Jennings and requested a postponement of his hearing. The date agreed on for the rescheduled hearing was April 21, 1978. On April 18, 1978, Dr. Doss' assistant advised Dr. Jennings' office that Dr. Doss had been involved in an automobile accident several weeks previously and, as a result, required surgery scheduled for April 19, 1978. A postponement was granted, and Dr. Doss' hearing was rescheduled for June 16, 1978. At the request of Dr. Doss, his hearing was again postponed.

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In a telephone conversation with Dr. Doss a new date was agreed on for scheduling his hearing, and by notice of July 17, 1978, his hearing was scheduled for August 17, 1978. Once again, Dr. Doss requested postponement because his health would not permit him to attend a hearing. Over the next four months Dr. Doss' office was contacted periodically. On November 21, 1978, we were advised that Dr. Doss' health had improved and he had resumed his medical practice.

By letter of November 22, 1978, Dr. Doss was offered seven alternative dates in January 1979, on which we were willing to schedule his hearing (Dr. Doss was also advised that Dr. Jennings was leaving the Agency and the Commissioner had designated Dr. Mark Novitch to preside at his hearing). No response was received from Dr. Doss. A follow-up telegram was sent to Dr. Doss on December 12, 1978. No response was received. By notice of December 20, 1978, the date of January 24, 1979, was designated by the presiding officer as the date for Dr. Doss' hearing. On January 19, 1979, the presiding officer contacted Dr. Doss concerning his intentions in regard to the hearing. At that time, Dr. Doss advised that he was physically unable to attend and requested a postponement. A wire to that effect was sent to the presiding officer by Dr. Doss on the same date. By letter of January 29, 1979, so that he could decide how to proceed in the matter, the presiding officer requested Dr. Doss to secure a statement from his physician as to his physical condition and as to the physician's prognosis as to when Dr. Doss would be able to attend a hearing. No response to that request was received from Dr. Doss.

By letter of April 11, 1979, (Att 1) the presiding officer notified Dr. Doss that he was scheduling Dr. Doss' hearing for May 15, 1979. The letter further advised that if a written reply was not received from Dr. Doss by May 1, either providing a statement from his physician describing his medical condition or Dr. Doss' agreement to the May 15 hearing it would be considered as a refusal by Dr. Doss to a reasonable opportunity for hearing. No response to the presiding officer's April 11 notice was received by May 1 (or since) from Dr. Doss.

RECOMMENDATION

The deficiencies in Dr. Doss' conduct of investigational drug studies are set forth in the Bureau of Drugs' November 15, 1977, letter to Dr. Doss (Att 2). The explanations of these deficiencies offered at his December 19, 1977, conference with the Bureau were considered unacceptable. Because Dr. Doss has declined to

excercise his opportunity for a regulatory hearing on the Bureau's determination, I recommend that the Commissioner find, based on the present record, that Dr. Doss has deliberately or repeatedly failed to comply with the exempting provisions for investigational-use drugs. The April 11 letter to Dr. Doss provided notice of the action being recommended in this report, and the reasons for the recommendation. Dr. Doss is not presently involved in the study of investigational drugs. He does continue to operate a

Accordingly, I recommend that Dr. Doss be notified by letter of his disqualification and that the letters to the sponsors of Dr. Doss' clinical studies notifying them of Dr. Doss' disqualification should issue.


Mark Novitch, M.D.

Attachments

- Att. 1 - April 11, 1979 Notice of Hearing
- Att. 2 - November 15, 1977 letter outlining deficiencies